

**DETAILED ACTION**

***Status of the Application***

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/09 has been entered.

[2] Claims 1-3, 5-8, and 10-16 are pending in the application.

[3] Applicant's amendment to the claims, filed on 3/12/09, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[4] All outstanding rejections and/or objections are withdrawn in view of the claim amendment filed on 3/12/09 and the instant examiner's amendment.

***Examiner's Amendment to the Specification***

[5] An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

[6] The abstract is re-written in its originally-filed form except as a single paragraph, rather than two paragraphs as follows:

Soyasapogenol B is biosynthesized via two steps of hydroxylation reaction of its precursor  $\beta$ -amyrin. However, the gene of the hydroxylase concerned in this reaction has not been revealed. Therefore, it was impossible to apply a genetic engineering technique on the hydroxylase. The present inventors reveals that a sequence which corresponds to a soybean-derived cytochrome P-450 gene CYP93E1 encodes an enzyme protein that carries out hydroxylation of the 24-position of an oleanane type triterpene, and also provides a method for applying said gene making use of a genetic engineering technique.

***Examiner's Amendment to the Claims***

**[7]** An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms Tu A. Phan on 4/3/09.

**[8]** Amend claims 1, 3, 5-6, 8, 10, and 12-16 as follows:

Claim 1. An isolated expression vector comprising a polynucleotide encoding the polypeptide of SEQ ID NO:9, wherein the polypeptide of SEQ ID NO:9 hydroxylates the 24-position of an oleanane-type triterpene.

Claim 3. A microorganism transformed with the expression vector of claim 1.

Claim 5. The microorganism of claim 3, wherein the microorganism is a yeast.

Claim 6. An isolated co-expression vector comprising a polynucleotide encoding the polypeptide of SEQ ID NO:9 and a  $\beta$ -amyrin synthase gene.

Claim 8. A microorganism transformed with the expression vector of claim 6.

Claim 10. The microorganism of claim 8, wherein the microorganism is a yeast.

In claims 12 and 13, replace --- transformant --- with --- microorganism ---.

Claim 14. A method for hydroxylating the 24-position of an oleanane-type triterpene, comprising culturing the microorganism of claim 3 in the presence of an oleanane-type triterpene, thereby hydroxylating the 24-position of the oleanane-type triterpene.

Claim 15. A method for hydroxylating the 24-position of an oleanane-type triterpene, comprising culturing the microorganism of claim 8 in the presence of an oleanane-type triterpene, thereby hydroxylating the 24-position of the oleanane-type triterpene.

Claim 16. A method for hydroxylating the 24-position of an oleanane-type triterpene, comprising culturing the yeast mutant strain of claim 11 in the presence of an oleanane-type triterpene, thereby hydroxylating the 24-position of the oleanane-type triterpene.

#### ***Notice of Rejoinder of Withdrawn Claims***

**[9]** Claims 3, 8, and 11 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 12-16, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on 1/30/08 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to

provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Examiner's Reasons for Allowance***

[10] The closest prior art of record is the reference of Steele et al. (cited in the IDS filed on 8/25/06), which teaches an expression vector comprising a nucleic acid that is 99.7% identical to SEQ ID NO:8, encoding a triterpene hydroxylase polypeptide that is 99.8% identical to SEQ ID NO:9. See paragraph 14 at pages 18-19 of the Office action mailed on 4/11/08. However, the examiner can find no teaching or suggestion in the prior art of record to modify the nucleic acid of Steele so that it encodes the polypeptide of SEQ ID NO:9 herein. As such, claims 1-3, 5-8, and 10-16, drawn to expression vectors comprising a polynucleotide encoding SEQ ID NO:9, transformed microorganisms, methods for producing a polypeptide, and methods for hydroxylating the 24-position of an oleanane-type triterpene, are allowable over the prior art of record.

It is noted that the expression vector of claim 6 requires a "β-amylin synthase gene" without recitation of a structural limitation. However, numerous species of such genes from a variety of organisms were well-known in the prior art (see, e.g., the reference of Morita et al., cited in the Form PTO-892 mailed on 4/11/08) and a patent specification need not teach, and preferably omits, what is well known in the art. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94

(Fed. Cir. 1986) and *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005).

Also, it is noted that claim 11 is drawn to a novel yeast mutant strain deposited as FERM BP-10201 with an acceptable International Depository Authority (MPEP 2405). See specification at p. 21, paragraph 29. According to a paper filed on 7/31/08, the microorganism has been deposited under the terms of the Budapest Treaty and in that same paper a statement has been provided that restriction on availability of the deposited microorganism will be irrevocably removed upon issuance of a patent.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David J. Steadman/  
Primary Examiner, Art Unit 1656